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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,458	02/11/2000	Michael R. Rosen	61020-A/HOW/PJP	6325

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/505,458

Applicant(s)

ROSEN ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment in Response to 2/22/02 Office Action

1. Claims 5, 9, 10, 12, 21, 24, 31, 34, 40, 43, 47, 48 and 50 were successfully amended to address the 35 U.S.C. 101 rejections and 35 U.S.C. 112 rejections of record. The objections to the specification and claim 50 were also successfully amended.

In the 2/22/02 Office Action, the Examiner required the Applicant to place the reference list found in specification in an appendix. The Applicant is unaware of any statute, regulation or MPEP section that prohibits listing of references in the specification and has followed this practice for many years in other applications without objection. The Examiner views disclosing pertinent prior art by referencing publications in the application and including full citations in the specification as improper. When references are viewed as disclosures of pertinent information, an Information Disclosure Statement is used. To be properly considered, the references must be included in an Information Disclosure Statement and the list of references removed from the specification.

The Applicant's arguments with respect to claims 1-60 have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

3. Claims 1, 9-11, 20, 28-30, 39 and 47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Ben-Haim et al. (US 6363279).

Ben-Haim et al. teach a method of modifying the force of contraction of a heart by applying a non-excitatory electrical field. The mechanical activation of the heart is controlled by electrical stimulation where action potentials from the S-A node enter the heart conduction system and propagate through the ventricles of the heart by sequentially activating connected muscle fibers (c 1, ll 31-45). This invention focuses on controlling the heart by modifying the action potentials, the ionic pumps and the channels of the heart (c 2, l 6 – c 3, l 32).

This invention focuses on controlling the heart by modifying the channels that connect the heart; the channels are read to include gap junction channels (c 2, l 6 – c 3, l 32). According the Ben-Haim et al., these channels of the heart are modified by electrical stimulation (c 27, ll 12-27; c 27, ll 52-57; c 31, ll 1-5). While Ben-Haim addresses the controlling the channels of the heart, the gap junctions channels are not specifically mentioned. It is however inherent that Ben-Haim et al. invention controls the gap junction channels as they are an essential component of the heart conduction system as noted in the art made of record (Winslow et al. US 5947899, c5, l 28 – c 6, l 3 and c 6, ll 33-53).

Refractory periods are modified by electrical stimulation (c 8, ll 3-5; c 8, l 66 – c 9, l 3; c 9, ll 15-19; c 17, ll 26-35; c 17, ll 45-46; c 31, ll 26-31; c 47, ll 37-45).

Ion channels are modified by electrical stimulation (c26, l 62 – c 27, l 27; c 27, ll 43-57; c 31, ll 1-5).

Changes in the heart occur over time as the heart is remodeled (c 9, ll 51-55; c 38, l 48 – c 39, l 10). Electrodes can be attached by sewing (c 30, ll 9-12). Electrodes can be placed in the heart or in vessels (c 37, ll 30-35 and c 40, ll 48-51). Electrodes can be activated in pairs (c 37, ll 15-17).

Claim Rejections - 35 USC § 103

4. Claims 2, 5, 12, 13, 15, 21, 24, 31, 32, 34, 40, 43, 50, 51, 53 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (US 5681308).

As discussed in paragraph 3 of this action, Ben Haim et al. disclose the claimed invention except for the 7cm x 1 cm (claims 4, 23 and 42) strip (claims 2, 13, 21, 32, 40 and 51) of electrode material having linked multiple electrode pairs, where the pairs are arranged in two columns (claims 12, 31 and 50) with one electrode in each pair in one column and the other electrode in each pair in the other column (claims 5, 15, 24, 34, 43, 53 and 58-60).

Edwards et al. disclose an analogous mapping apparatus and teach that it is known to use a circuit (38) mounted on a membrane support (16) to serve as a cardiac electrode which provides columns of individually controlled treatment electrodes (34) which can be multiplexed to enable stimulation of electrode pairs (figure 7 and c 7, ll 38-52). Absent any teaching of criticality or unexpected results, it is understood the electrode can be configured as a 7cm x 1 cm strip with only two columns of electrodes. The configuration change is an obvious change in shape based on the specific application. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for modifying the force of contraction of a

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heart as taught by Ben-Haim et al., with the electrode as taught by Edwards et al. to provide a flat electrode with multiple electrode measurement and stimulation configurations so the cardiac tissue can be more effectively treated.

5. Claims 3, 4, 14, 17-19, 22, 23, 33, 36-38, 41, 42, 52 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) and Edwards et al. (5681308) in view of Dahl et al. (US 5203348).

As discussed in paragraphs 3 and 4 of this action, modified Ben-Haim et al. disclose the claimed invention except for:

- the electrode strip of polyurethane (claims 3, 14, 22, 33, 41, and 52),
- the electrode comprised of platinum or consisting essentially of unalloyed platinum (claims 17-18, 36-37 and 55-56), and
- the electrode connected to insulated stainless steel wire (claims 19, 38 and 57).

Dahl et al. disclose an electrode and teaches that it is known to fabricate an electrode with a platinum or platinum alloy conductor or conductor with a stainless steel core (c 5, ll 19-36), and a lead with a medical grade polyurethane sheath and a stainless steel coated conductor (c 5, ll 23-38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the materials of construction as taught by Dahl et al.. One have ordinary skill in the art would have been motivated to make such a modification in electrode to specify materials of construction that have proven electrical properties.

6. Claims 7, 8, 26, 27, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Dahl et al. (US 5203348).

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As discussed in paragraph 3 of this action, Ben-Haim et al. disclose the claimed invention except for the electrode comprised of platinum or consisting essentially of unalloyed platinum.

Dahl et al. disclose an electrode and teaches that it is known to fabricate an electrode with a platinum or platinum alloy conductor (c 5, ll 23-38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the platinum or platinum alloy conductor as taught by Dahl et al.. One having ordinary skill in the art would have been motivated to make such a modification in electrode to specify materials of construction that have proven electrical properties.

7. Claims 6, 16, 25, 35, 44 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) and Edwards et al. (US 5681308) in view of Ideker (US 5873896).

As discussed in paragraphs 3 and 4 of this action, modified Ben-Haim et al. disclose the claimed invention except for the electrode pair being 2mm from each other and the electrode pairs being spaced at least 5 mm apart.

Ideker teaches a cardiac device for reducing arrhythmias and teaches that it is known to use an electrode configuration of an elongate primary strip with a plurality of electrodes positioned at spaced intervals, e.g. 1-4 millimeters (c 3, ll 2-4). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method for modifying the force of contraction of a

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heart as taught by Ben-Haim et al., with the electrode spacing as taught by Ideker to provide electrode spacing known to effectively reduce cardiac arrhythmias.

Other Prior Art Cited

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5947899 to Winslow et al. teaches electrical dynamics of the heart including gap junction channels.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, telephone number (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FP
8/23/02

[Signature]
JEFFREY R. JASTRZAB
PRIMARY EXAMINER
3762
10/24/02